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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HUMPHREY, DAVID HAROLD	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 02/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/678,639	HE ET AL.	
	Examiner	Art Unit	
	David Humphrey	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Sequence Compliance

1. The specification and claims are objected to for failing to adhere to the requirements of the sequence rules. Applicant must append SEQ ID Nos. to all mentions of specific sequences in the specification and the claims. See 37 CFR § 1.821(d). Claims 19-23 refer to CDRs of a VH or VL chain in figure 7. Each of the VH and VL chains referred to in the claims must be represented by a unique SEQ ID NO. For example, it is not clear which clone listed in figure 7 corresponds to SEQ ID NO:2. Full compliance is required in response to this Restriction Requirement. A reply that fails to comply will be considered to be non-responsive and may result in abandonment of this application.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 8-11, and 17, drawn to a method of inhibiting the growth of a cancer cell that overexpresses a Wnt protein wherein the Wnt protein is Wnt-1, classified in class 424, subclass 135.1.

II. Claims 1-3, 5, 8-11, and 17, drawn to a method of inhibiting the growth of a cancer cell that overexpresses a Wnt protein wherein the Wnt protein is Wnt-2, classified in class 424, subclass 135.1.

III. Claims 1, 2, 6, 7-11, and 17, drawn to a method of inhibiting the growth of a cancer cell by contacting the cell with an antibody

specifically binds a Frizzled receptor, classified in class 424, subclass 143.1.

IV. Claims 1 and 12-15, drawn to a method of inhibiting the growth of a cancer cell in a patient by administering an anti-Wnt-1 antibody to the patient and a second therapeutic agent which is a chemotherapeutic agent, classified in class 435, subclass 7.23.

V. Claims 1, 12-14, and 16, drawn to a method of inhibiting the growth of a cancer cell in a patient by administering an anti-Wnt-1 antibody to the patient and a second therapeutic agent which is radiation therapy, classified in class 600, subclass 310.

VI. Claims 1 and 12-15, drawn to a method of inhibiting the growth of a cancer cell in a patient by administering an anti-Wnt-2 antibody to the patient and a second therapeutic agent which is a chemotherapeutic agent, classified in class 424, subclass 155.1.

VII. Claims 1, 12-14, and 16, drawn to a method of inhibiting the growth of a cancer cell in a patient by administering an anti-Wnt-2 antibody to the patient and a second therapeutic agent which is radiation therapy, classified in class 600, subclass 310.

VIII. Claims 1, 12-15, drawn to a method of inhibiting the growth of a cancer cell in a patient by administering an anti-Frizzled receptor antibody to the patient and a second therapeutic agent which is a chemotherapeutic agent, classified in class 424, subclass 277.1.

IX. Claims 1, 12-14, and 16, drawn to a method of inhibiting the growth of a cancer cell in a patient by administering an anti-Frizzled receptor antibody to the patient and a second therapeutic agent which is radiation therapy, classified in class 600, subclass 310.

X. Claims 18-20, drawn to an anti-Wnt1 monoclonal antibody that specifically binds to a peptide of SEQ ID NO:2 wherein the VH comprises one CDR of a VH chain shown in figure 7, classified in class 424, subclass 130.1.

XI. Claims 18, 19, 21, and 24-27, drawn to an anti-Wnt1 monoclonal antibody that specifically binds to a peptide of SEQ ID NO:2 wherein the VH comprises all three of the CDRs of a VH chain shown in figure 7, classified in class 424, subclass 138.1.

XII. Claims 18, 19, 22, and 24-27, drawn to an anti-Wnt1 monoclonal antibody that specifically binds to a peptide of SEQ ID NO:2 wherein the VL comprises a CDR of a VL region shown in figure 7, classified in class 424, subclass 138.1.

XIII. Claims 18, 19, 23, and 24-27, drawn to an anti-Wnt1 monoclonal antibody that specifically binds to a peptide of SEQ ID NO:2 wherein the VL comprises all three of the CDRs of a VL region shown in figure 7, classified in class 424, subclass 138.1.

XIV. Claims 18-20, and 24-27, drawn to an anti-Wnt1 monoclonal antibody that specifically binds to a peptide of SEQ ID NO:4

wherein the VH comprises one CDR of a VH chain shown in figure 7, classified in class 424, subclass 130.1.

XV. Claims 18, 19, 21, and 24-27, drawn to an anti-Wnt1 monoclonal antibody that specifically binds to a peptide of SEQ ID NO:4 wherein the VH comprises all three of the CDRs of a VH chain shown in figure 7, classified in class 530, subclass 387.7.

XVI. Claims 18, 19, 22, and 24-27, drawn to an anti-Wnt1 monoclonal antibody that specifically binds to a peptide of SEQ ID NO:4 wherein the VL comprises a CDR of a VL region shown in figure 7, classified in class 424, subclass 130.1.

XVII. Claims 18, 19, 23, and 24-27, drawn to an anti-Wnt1 monoclonal antibody that specifically binds to a peptide of SEQ ID NO:4 wherein the VL comprises all three of the CDRs of a VL region shown in figure 7, classified in class 424, subclass 138.1.

XVIII. Claims 18-20, and 24-27, drawn to an anti-Wnt2 monoclonal antibody that specifically binds to a peptide of SEQ ID NO:9 wherein the VH comprises one CDR of a VH chain shown in figure 7, classified in class 424, subclass 278.1.

XIX. Claims 18, 19, 21, and 24-27, drawn to an anti-Wnt2 monoclonal antibody that specifically binds to a peptide of SEQ ID NO:9 wherein the VH comprises all three of the CDRs of a VH chain shown in figure 7, classified in class 424, subclass 141.1.

XX. Claims 18, 19, 22, and 24-27, drawn to an anti-Wnt2 monoclonal antibody that specifically binds to a peptide of SEQ ID NO:9 wherein the VL comprises a CDR of a VL region shown in figure 7, classified in class 424, subclass 139.1.

XXI. Claims 18, 19, 23, 24-27, drawn to an anti-Wnt2 monoclonal antibody that specifically binds to a peptide of SEQ ID NO:9 wherein the VL comprises all three of the CDRs of a VL region shown in figure 7, classified in class 424, subclass 139.1.

XXII. Claims 28-30, drawn to a method of screening for an agent that inhibits the proliferation of a cancer cell, the method comprising contacting the agent with a Dv1 protein, classified in class 435, subclass 7.1.

XXIII. Claims 31-34, drawn to a method of inhibiting the growth of a cancer cell that overexpresses a Dv1 protein, classified in class 435, subclass 7.21.

XXIV. Claim 35, drawn to a method of inhibiting the growth of a cancer cell that overexpresses a Wnt or frizzled protein, the method comprising contacting the cell with an agent that binds to the intracellular domain of a Frizzled receptor, classified in class 424, subclass 143.1.

3. The inventions are distinct, each from the other because of the following reasons:

The methods of Inventions I-IX, and XXII-XXIV are separate and distinct. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: they have distinct method objectives, method parameters and steps, and utilize patentably distinct reagents. Inventions I-III, IV-IX, XXII, XXIII, and XXIV are separate and distinct methods due to their distinct method objectives. Although Inventions I-III have the same method objective, inhibiting the growth of a cancer cell, each invention utilizes a distinct pathway. For example, Invention I requires an antibody that binds Wnt-1 whereas Invention II requires antibody that binds Wnt-2. Invention III utilizes an antibody that binds a Frizzled receptor which is not required for Inventions I and II. Although Inventions IV-IX have the same method objective, inhibiting the growth of a cancer cell in a patient, each invention utilizes distinct reagents and method steps. For example, Invention IV requires the addition of an anti-Wnt-1 antibody and a chemotherapeutic agent whereas Invention V requires an anti-Wnt-1 antibody and radiation therapy. Similarly, Invention VI requires the addition of an anti-Wnt-2 antibody and a chemotherapeutic agent whereas Invention VII requires an anti-Wnt-2 antibody and radiation therapy. In additions, Invention VIII requires the addition of an anti-Frizzled antibody and a chemotherapeutic agent whereas Invention IX requires an anti-Frizzled antibody and radiation therapy. Therefore, the methods of Inventions IV-IX are patentably distinct. As mentioned above, methods XXII, XXIII, and XXIV have separate and distinct method objectives. Invention XXII is drawn to a

method of screening for an agent. Invention XXIII is drawn to a method of inhibiting the growth of a cancer cell that overexpresses a Dv1 protein whereas Invention XXIV is drawn to a method of inhibiting the growth of a cancer cell by contacting the cell with an agent that binds to the intracellular domain of a Frizzled receptor. Therefore, Inventions I-IX, and XXII-XXIV are patentably distinct.

The products of Inventions X-XXI are patentably distinct. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P § 806.05 for inventive groups that are directed to different products, restriction is deemed proper because these products constitute patentably distinct inventions for the following reasons. Groups X-XXII are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. For example, the antibodies of Inventions X-XIII, XIV-XVII, XVIII-XXI, bind to patentably distinct sequences, SEQ ID NO's: 2, 4, and 9, respectively. The antibodies of Inventions X-XIII are products that bind to a peptide of SEQ ID No:2 but have distinct structural properties. The antibody of Invention X has one CDR of a VH chain where as the antibody of Invention XI contains all three CDRs of a VH chain. The antibodies of Inventions XII and XIII recite physical properties that are not required for the antibodies of Inventions X and XI, namely that they contain one CDR of a VL region or all three CDRs of a VL region. Similarly, the antibodies of Inventions XIV, XV, XVI and XVII are patentably distinct as are the antibodies of Inventions XVIII, XIX, XX, and XXI. Since Inventions I-XXVI are patentably distinct, a search of all groups would pose an undue search burden on the USPTO's resources.

Inventions X-XVII and I, IV, and V, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibodies of Inventions X-XVII can be used to purify the Wnt-1 protein.

Inventions XVIII-XXI and II, VI, and VII, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibodies of Inventions XVIII-XX1 can also be used to purify the Wnt-2 protein.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Humphrey whose telephone number is (571) 272-5544. The examiner can normally be reached on Mon-Fri 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Humphrey, Ph.D.

January 23, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER